Stem cell-derived islet cell replacement therapy with immunosuppression for high-risk type 1 diabetes

Grant Award Details

Stem cell-derived islet cell replacement therapy with immunosuppression for high-risk type 1 diabetes

Grant Type: Late Stage Preclinical Projects

Grant Number: CLIN1-08671

Project Objective: To manufacture cell product, execute pre-clinical GLP studies, and submit IND application to the FDA to allow clinical testing of VC-02 device.

Investigator:

Name:	Kevin D'Amour
Institution:	ViaCyte, Inc.
Type:	PI

Disease Focus: Diabetes, Metabolic Disorders, Type 1 diabetes

Human Stem Cell Use: Embryonic Stem Cell

Award Value: $3,544,721

Status: Closed

Progress Reports

Reporting Period: OM #1

View Report

Reporting Period: OM #2

View Report

Grant Application Details

Application Title: Stem cell-derived islet cell replacement therapy with immunosuppression for high-risk type 1 diabetes

Public Abstract:

Therapeutic Candidate or Device

hESC-derived pancreatic progenitor cells delivered in a device that allows direct vascularization of the cell therapy

Indication

high-risk type 1 diabetes including "brittle" diabetes and hypoglycemia unawareness

Therapeutic Mechanism

People with type 1 diabetes have lost their pancreatic cells that make insulin, and therefore have to self-administer insulin. It is very difficult to manage blood sugar to safe levels by this method. Chronically too high can lead to blindness, kidney failure, nerve damage, and heart problems, and too low can cause coma or death. This product will replace the lost pancreatic cells and provide a natural biological ability to maintain stable healthy blood sugar levels.

Unmet Medical Need

There are over 100,000 people in the US with type 1 diabetes so severe that they are at constant risk of hospitalization and/or death. Within months after administration, this product could naturally restore those patients' blood sugar to normal healthy levels and save their lives.

Project Objective

complete pre-clinical work and file IND

Major Proposed Activities

- manufacture and quality control assessment of the cells and devices for pre-clinical and clinical studies
- execute GLP pre-clinical safety study
- prepare and submit IND application to FDA to allow clinical testing of VC-02

Statement of Benefit to California:

The product will be available through clinical trials in California & if approved by the FDA for commercial use, will help many thousands of Californians with high-risk diabetes. The product will save lives and increase quality of life for patients/families, while significantly reducing the state's health care burden. Indeed the product could become the most significant stem cell-based medical treatment of the coming decade; a tremendous achievement for California, its taxpayers, and CIRM.

Source URL: https://www.cirm.ca.gov/our-progress/awards/stem-cell-derived-islet-cell-replacement-therapy-immunosuppression-high-risk